Reduction of downtime through the design of TPM and the implementation of some techniques of SMED system at high speed packaging lines

Dorcas Y. López López
Ralfy Calo Ortiz
Edwin G. Pérez Carrión
José J. Marrero Laboy
Graduation candidates in industrial engineering, PUPR

Abstract

This project was developed at a pharmaceutical facility located in the eastern area of Puerto Rico. The company manufactures oral contraceptives and analgesics. In the analgesic branch a new product is being introduced, and two packaging lines were acquired. Together both lines, called OTC-1 and OTC-2, pack six product presentations. The OTC-1 line packs four presentations that are distributed as follows: 50 count (oval and round) and 100 count (oval and round). The OTC-2 line packs a 24 count (oval and round).

Our project consisted of two stages. First we studied the actual conditions of the machinery for the lines. Afterwards we pointed out the opportunities that would help us achieve our goal: improving the available time for production in the two high-speed packaging lines. To achieve this goal we planned the design of total productive maintenance (TPM) and implementation of a setup time reduction system known as single minute exchange of die (SMED).

Sinopsis

Este proyecto se realizó en una industria farmacéutica del este de Puerto Rico que se dedica a producir anticonceptivos y analgésicos. En la rama de analgésicos se produce un nuevo producto, para lo cual se adquirieron dos líneas de empaque adicionales. Estas líneas, OTC-1 y OTC-2, empacan seis

To make a sample representative of the universe, it must contain the appropriate number of observations. The number of random observations (N) depends on:

a. the desired relative accuracy (A)
b. the desired confidence level
c. The proportion of occurrence (P)

The accuracy expected for this study was 10% at a confidence level of 90%. Equation (1) was used to calculate the number of observations.

$$N = \frac{(1.65)^2 * (1 - P)}{A^2 * P} \quad (1)$$

For P = 2.5% (we want to identify 2.5% and up of the downtime causes) we calculated 10,881 random observations. With this number we can be certain 90% of the time (confidence level) that our results are 10% close (relative accuracy) to the real figure for all activities that comprise the packaging line performance.

Design and execution of the work sampling study

A practical way of studying and analyzing the work performed at the two high speed packaging lines was to use work sampling. The sections that follow detail the work sampling study as it was designed and executed for the lines. A list of all possible downtime causes per machine was made with the assistance of the operators, log books and supervisors.

<u>Observation summary sheet</u>

Data recorded in the daily observation sheet were summarized in the observation summary sheet. Accumulated percentages were calculated for each activity to be measured. The observation summary sheet collected all daily observations and converted them to percentages or minutes dedicated to a specific activity or downtime cause per day. Also, this form has different formulae to calculate the output per minute of the packaging line.

Results

A characteristic of the work sampling technique is its suitability to determine what portion of the total time is dedicated to a specific activity. According to our study, 65% of the total packaging time is downtime (fig. 1). Figure 2 presents the distribution of downtime during the time of the study.[2]

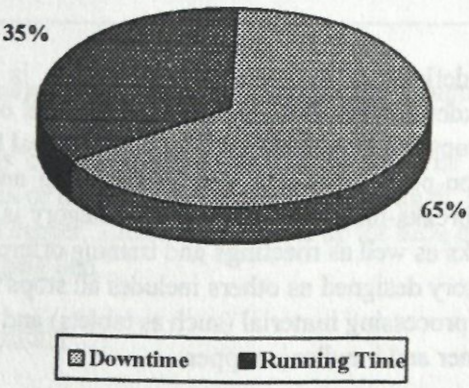

Figure 1. Total time dedicated to packaging

---

[2]Results obtained from a total of 13 days included in the study. This does not represent a typical work day.

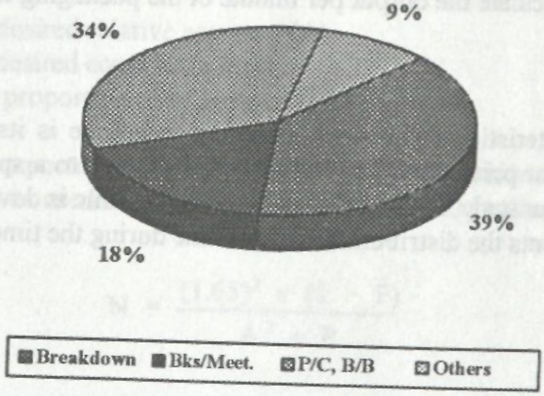

Figure 2. Distribution of downtime

Downtime, defined as the non-productive time, is divided into four categories: breakdown, P/C-B/B, breaks-meetings and others. Breakdown includes all interruptions in production due to mechanical failure, while P/C-B/B refers to non-productive time due to the setup and cleaning of the machinery. The breaks-meetings (Bks/Meet.) category is the time spent on regular daily breaks as well as meetings and training offered to the operators. Finally, the category designed as others includes all stops in production time related to lack of processing material (such as tablets) and to the changing of rolls in the cartoner and bundler/wrapper.

To identify the equipment with a greater breakdown percentage the Pareto technique was used. Figure 3 shows how the breakdown is distributed per machine.

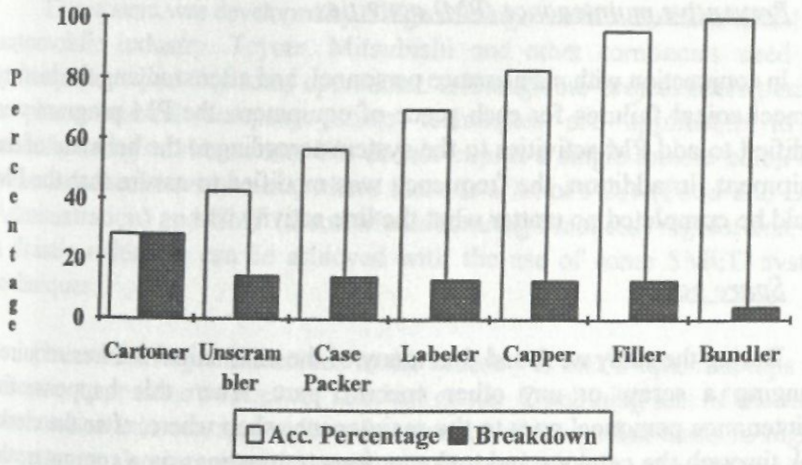

Figure 3. Breakdown distribution per equipment

On the basis of the Pareto, to reduce breakdowns it is necessary to analyze the causes of mechanical failures in the cartoner, unscrambler, case packer, labeler and capper. These failures make up for 82% of total breakdown time of the packaging line.

Recommendations

After analyzing the information obtained from the study, it was concluded that the inconsistencies in daily output were due to downtime. To assure a substantial increase in the daily production it is necessary to significantly reduce the breakdowns and the P/C and B/B. The best way of doing this is working through the causes of mechanical failures presented in this study and revising and improving the preventive maintenance of the equipment. A TPM would be the ideal tool for reducing breakdowns. On the other hand, the SMED system is useful in reducing setup time; it is also useful for reducing cleaning time.

Preventive maintenance (PM) activities

In conjunction with maintenance personnel, and after studying the history of mechanical failures for each piece of equipment, the PM program was modified to add PM activities to the system according to the behavior of the equipment. In addition, the frequency was modified to assure that the PM would be completed no matter what the line activity was.

Spare parts

During the study we found that many of the mechanical failures required changing a screw or any other specific part. When this happens, the maintenance personnel goes to the maintenance shop where, after the clerks look through the catalogs and make various transactions on a computer, the clerks provide them with the part they need. On many occasions the personnel had to wait before being served, or the part needed was not available, which meant more delays in fixing the line breakdown. The maintenance shop provided us a list of screws and parts most commonly used for the OTC packaging lines and we found that many items were not in inventory. Working together, the line mechanics and shop personnel updated the parts inventory, purchased those items out of stock and moved all screws to the packaging area, thus avoiding unnecessary delays. It was established that when the line was down, shop personnel would give priority to the mechanics over other people asking for service. Finally, work is being made on a catalog where all spare parts are illustrated to make it easier to find the part number.

What is SMED?

Single minute setups is popularly known as the SMED system, where SMED is an acronym for single minute exchange of die. The term refers to a theory and techniques for performing setup operations in less than 10 minutes. Although not every setup can literally be completed in less than 10 minutes, this is the goal of the system, and it can be met. Even when it cannot, dramatic reductions in setup time are usually possible.[3]

This system was developed by Shigeo Shingo for the Japanese metal and automobile industry. Toyota, Mitsubishi and other companies used this technique to reduce their setup operations. Although our project takes place in a pharmaceutical company, some techniques are applicable to all manufacturing environments. We do not expect a single minute setup in a pharmaceutical environment, where there is a lot of FDA (Food and Drug Administration) and GMP (Good Manufacturing Practices) regulations, but a drastic reduction can be achieved with the use of some SMED system techniques.

One of the major difficulties in the industry is that frequent setups are necessary to produce a variety of finished goods. Combining lots of the same presentation into one may reduce the number of setups but leads to higher inventory; it also increases the product lead time. We want a quick response to the demand, and large lots are not the answer. Even if the number of setups cannot be reduced, the setup time itself can be cut down. SMED defines two types of setups: an internal setup and external setup.

The internal setup is carried out when the machine is stopped. On the other hand, the external setup is done with the machine running. Also, SMED identifies four conceptual stages involved in setup improvements:

Preliminary stage:	internal and external setup conditions are not distinguished
Stage 1:	Separating internal and external setups
Stage 2:	Converting internal to an external setup
Stage 3:	Streamlining all aspects of the setup operations

---

[3]Shingo, Shigeo., A Revolution in Manufacturing: The SMED System, page xix, 3rd paragraph

Description of setup procedures (actual conditions)

The SMED technique is very useful when cutting down the time required for shifting machinery from manufacturing one product to another. Analgesic A has four presentations for line OTC -1 (50- and 100-jars). The OTC-1 packaging line has an approximate 65% downtime of which 34% is credited to changeover (B/B) and product change or what is commonly called the setup. A typical situation on an OTC-1 packaging line:

Packaging order #XX1 - 125k units (100 count, oval tablet)
Packaging order #XX2 - 200k units (50 count, round tablet)
Packaging order #XX3 - 150k units (100 count, round tablet)

This trend makes an average of four setups per week. Our objective is to increase production time, so changeover and product change has to be decreased. There are three types of changes on the packaging line:

1. Changeover (B/B)

A changeover occurs when the size of jars is changed. In our case, only the OTC-1 packaging line goes through a jar size change (from a 50 count to a 100 count or viceversa). The OTC-2 packaging line is dedicated to the production of the 24 count, although eventually it will package the 50 count jar. During changeover the floor is cleaned with a germicide, the interior and exterior surfaces of each machine and the adjacent areas are cleaned (chairs and tables). The excess dust is suctioned by vacuum cleaners and stuck material is removed with compressed air hoses. After finishing the cleanup of each piece of equipment, the mechanics on shift proceed to change the parts and make the necessary adjustments in size that correspond to the size of the jar to be packaged. During the whole process, different forms are filled out for the final approval of the line. The standard time for changeover is eight hours.

Timing charts

One of the most useful tools in improving changeover times is the timing chart. The timing chart is a pictorial representation of all the activities associated with the changeover laid out over time. During the first stage we used this tool to separate the activities of the internal and external setups. With the help of the operators and the protocol we defined the activities performed during the setup time and how much time each one took.

2. Product change

As the name suggests this is a change of a product, when one type of tablet package order is finished and another type of tablet is to be started (from oval to round or viceversa). During this type of change, parts are removed from the filler machine and taken to a wash station for cleaning. Together with these cleaned parts, the parts corresponding to the new order are brought in. During this time the floor is cleaned with a germicide; so as are the interior and exterior surfaces of each machine and the adjacent areas (chairs and tables). The excess dust is suctioned by vacuum cleaners and stuck material is removed with compressed air hoses. During the entire process, different forms are filled out for the final approval of the line. The standard time for product change is eight hours.

3. Back-to-back

Back to back change is carried out when a packaging line order is followed by another for the same product. In this case only the codification of the lot is changed. During the cleanup the operators remove all material from the last lot and clean all equipment with compressed air to remove any stuck component or tablet. They remove excess dust and clean with a germicide the interior surfaces of each machine, floor and adjacent areas (tables and chairs). Then they transport the packaging components and tablets that will be used in the next packaging order. During the entire process different forms are filled out for the final approval of the line. The standard time for this cleaning is three hours. We do not include this cleaning in our project (there are no mechanical setups) but there are improvements in this category; from 3 hours, presently the performance is 1.5 hours.

Description of the OTC packaging line

OTC is a high speed packaging line made up of eight machines whose function is to complete the last stage of the product manufacturing process. It extends from the filling of the jars to the stage of completing the pallets with shippers (fig. 4). Table 2 shows the distribution of operators in the OTC line.

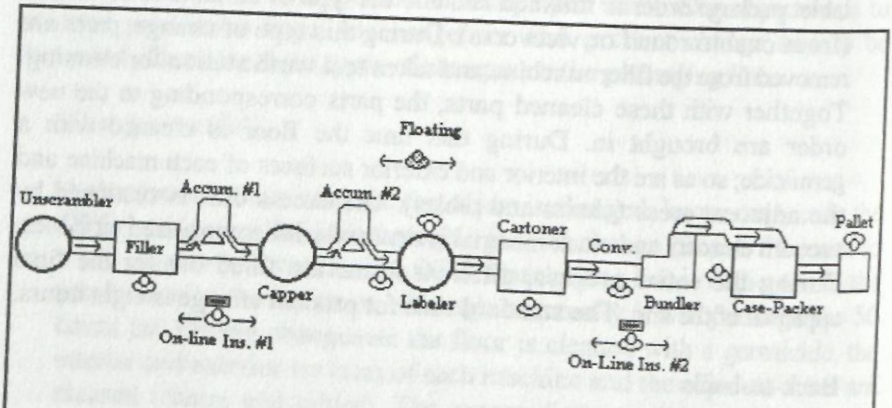

Figure 4. OTC top view

Table 2. Positions in the OTC line and number of operators assigned

Position	Operators assigned
Unscrambler - filler	1
Capper - sealer	1
Labeler	1
Cartoner	1
Conveyor	1
Bundler - case packer	1
On-line inspector	2
Floating (material handlers)	1

Each operator is responsible for his equipment, including speed setup and the cleanup in each change presentation. The function of the operator assigned to the conveyor is to inspect the sealing and printing on the boxes that leave the cartoner. The function of the on-line inspector is to audit the product quality during the entire packaging process. The OTC lines adopted a quality assurance system that requires minimum supervision and intervention from the Quality Assurance Department.

Preliminary stage: Internal and external set up are not distinguished

In this phase we collected all the necessary information on how the changes on the OTC lines were made. Work sampling, primarily designed to determine causes of downtime was a decisive tool for recording floor observations of the changeover and product change process, considering that we spent eight hours daily for three weeks gathering data. Together with this information and the complete study of the protocols and procedures of the area, we obtained a better understanding of changes on the OTC packaging line. To this we can add the valuable information obtained from the operators during weekly meetings with them.

During the changeover and product change procedures, multiple tasks were performed. On many occasions activities that could have been completed before or after the change were completed during the change, making it more extensive. Tasks such as looking for buckets and other cleaning equipment (mops, wash clothes and others), looking for labels for the reject stations, the retrieval of material, transportation of material for the next order and documentation, all made us observe that changeover time would be greatly reduced by implementing a technique such as SMED. Lack of organization was evident between the operators; we observed that the same task was done twice by two different persons. Figures 5 and 6 show the product change and back to back (changeover) timing charts respectively.

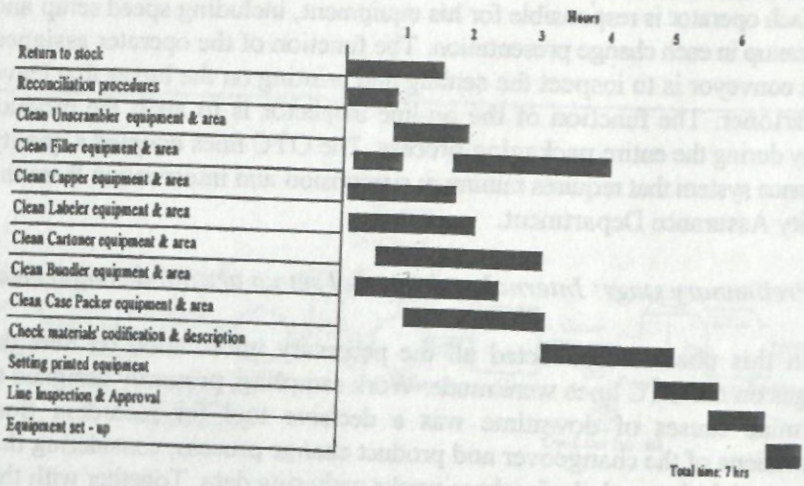

Figure 5. Product change timing chart

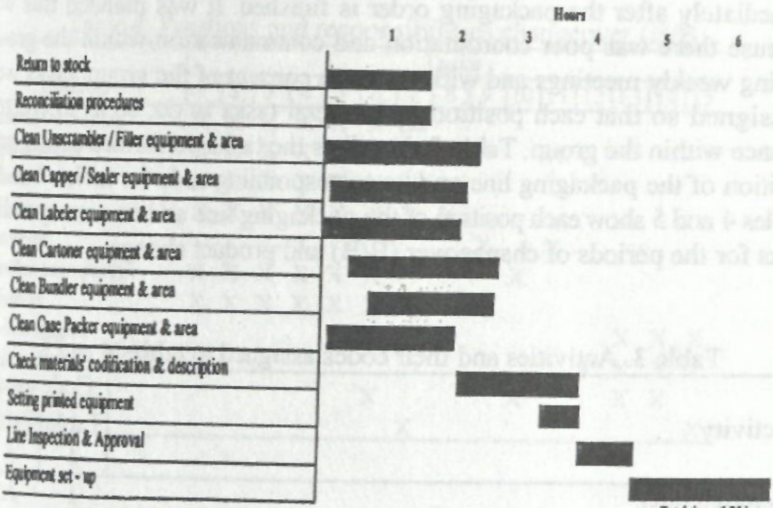

Figure 6. Changeover timing chart

Stage 1: Separating internal and external setups

In this stage each activity is listed according to its position in the cleaning period. With the timing chart tool we identified the internal and external setup for the cleanup of each equipment. Given that the pharmaceutical industry is guided by regulations of agencies such as the FDA, many activities that could be external setups, such as transportation of materials assigned to the packaging order, cleanups, inspections, approvals and a great deal of the documentation, must be included as internal setups. This means that these activities could be done once the lot is completed and leaves the line, which means the machinery is stopped. Given that cleanup activities take up a great part of the changeover time, we will analyze them in more detail. In order to establish parallel activities, all the tasks performed during changeover were listed, so as to coordinate the personnel and assign each activity to be done immediately after the packaging order is finished. It was planned this way because there was poor coordination and communication within the group. During weekly meetings and with common consent of the group, tasks were reassigned so that each position had several tasks to do, so as to create a balance within the group. Table 3 describes the tasks performed during each position of the packaging line and its corresponding code for tables 4 and 5. Tables 4 and 5 show each position of the packaging line and its corresponding tasks for the periods of changeover (B/B) and product change.

Table 3. Activities and their codes assigned to tables 4 and 5

Activity	Code used	
	Table 4	Table 5
Remove dust	1	A
Remove material from previous lot	2	B
Clean with compressed air	3	C
Clean machine with germicidal solution	N/A	D
Clean floor, tables and chairs with germicidal solution	N/A	E
Clean conveyor	4	F
Document cleaning	5	G
Get next package order material	6	H
Set printing equipment	7	I
Get rejects to accounting	8	J
Support cartoner	9	K
Return to stock	10	L
Clean accumulators	11	M
Reconcile	12	N
Inspect and approve line	13	O
Dispose of waste	14	P
Support cleaning	15	Q

Table 4. Positions and responsibilities:changeover (B/B)

Position	Tasks														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Unscrambler-filler	X	X	X	X	X	X	n/a								
Capper-sealer	X	X	X	X	X	X					X				
Labeler	X	X	X	X	X	X	X								
Cartoner	X	X	X	X	X	X	X	X							
Conveyor				X					X		X				
Bundler-case packer	X	X	X	X	X	X				X					
Palletizer	X	X	X	X	X	X	X								
On-line stage 1													X	X	X
On-line stage 2												X	X	X	X
Floating						X				X			X	X	
Mechanics							X								X

Table 5. Positions and responsibilities:product change

Position	Tasks																
	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Unscrambler-filler	X	X	X	X	X	X	X	X									
Filler (on-line stage 1)	X	X	X	X	X	X	X										
Capper-sealer	X	X	X	X	X	X	X	X					X				
Labeler	X	X	X	X	X	X	X	X	X								
Cartoner	X	X	X	X	X	X	X	X	X	X							
Conveyor						X					X		X				
Bundler-case packer	X	X	X	X	X	X	X	X				X					
Palletizer	X	X	X	X	X	X	X	X	X								
On-line stage 1															X	X	X
On-line stage 2														X	X	X	X
Floating								X				X			X	X	
Mechanics									X								

Stage 2: Converting an internal setup to an external setup

After examining the operations within the product change and changeover processes, we determined that the operation of looking for cleaning materials (buckets, mops, etc.) in the wash station was an external setup activity inasmuch as the mechanic or housekeeper brought the cleaning cart before the package order was finished. This prevented operators from having to go out and spending from 10 to 12 minutes in bringing the cleaning equipment to the wash station. With each lot change and its respective cleanup, some parts are removed from each of the machines as well of their protective guards. The product change cleanup is a complete process because the tablet is changed and there is a risk of a product mix-up. Yet the changeover cleanup is more superficial and requires less caution since there is no chance for a product mix-up. In this case the most important thing to do is to clean the dust accumulated in the machines and any printed material or packaging components from the previous lot. On the basis of this fact and the fact that the only cleanup that goes through the validation process is the product change cleanup, the operations of cleaning the machine, the floor and the tables and chairs with a germicide solution are eliminated in the changeover. If, after using the vacuum cleaner, the wash cloths or compressed air or some equipment has dust, an atomizer with 70% diluted alcohol (which is part of the day to day materials on the line) can be used. Also, the operation of transporting the components assigned to the next package order was distributed among all of the operators.

In the past, the floating made all of the contacts with the warehouse personnel, verified the components and transported them to the line. This represented delays in starting the run, because the entrance of materials began after the equipment cleanup and ended when the dispatched components entered the packaging line. Now, each operator looks for the material of his respective machinery when he finishes the cleanup. This also accelerates the approval operation of the line by the on-line inspector, since each piece of equipment is approved once it is clean and has material for processing. The online inspector has a more active role during cleanups. The tasks are divided according to figures 5 and 6; while one reconciles the materials from the package order, the other assists in the cleanup of the unscrambler. During the product change, when the cleanup of the filler is more thorough, the online inspector that makes reconciliation proceeds to give support to the filler operator. Figures 7 and 8 show with more detail the improvement of the cleanup operation in changeover and product change.

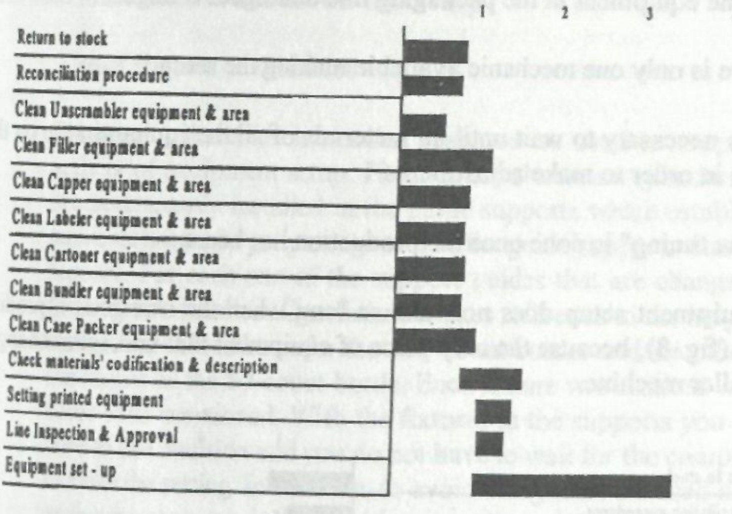

Figure 7. Changeover (B/B) improved.

Equipment setup time

As part of our strategy for reducing clean up time, in this stage we concentrated our efforts toward finding alternatives to reduce equipment set up on the OTC - 1 packaging line. Perhaps the most critical changeover activities within the presentation change of the product is the equipment set up. This is so because once the cleanup procedures are completed, the time the packaging line takes in recovering its normal production speed, 300 jars per minute (JPM), depends on how effective the setup was.

As figure 7 shows, the equipment set up is the most time consuming activity; it takes approximately 2.5 hours to complete. Some factors which contribute to long set up during changeover are:

- all the equipment in the packaging line undergoes changes
- there is only one mechanic available making the setup
- it is necessary to wait until all materials of all the equipment are on the line in order to make adjustments
- "fine tuning" is done once the production has begun

Equipment setup does not take so long when the change is a product change (fig. 8), because the only piece of equipment that undergoes changes is the filler machine.

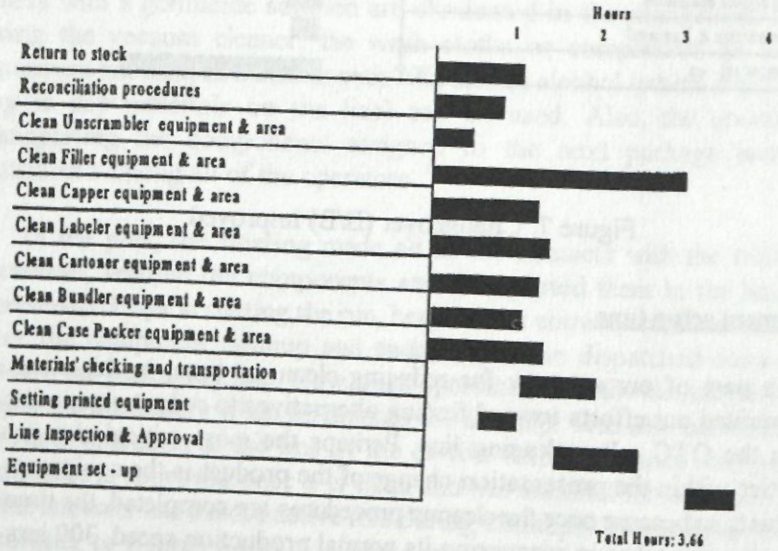

Figure 8. Product change improved

To reduce setup time it was necessary to make this activity as simple and organized as possible, requiring a minimum of mechanical skills. Among the tools used to accomplish this are the following:

- Use of fixtures or dummies

  Fixtures or dummies is another resource we used to simplify the activity of equipment setup. Fixtures are aluminum cylinders which are permanently installed in the guide supports which establish the conveyor height for jar passage and in the guide supports that fix the sensors. For each one of the support guides that are changed, two fixtures are installed. One fixture makes reference to the height that each guide should have for the 100-count bottles and the other with the height of the 50-count bottle. Each fixture was marked with the color code mentioned. With the fixtures in the supports you do not have to use intuition and you do not have to wait for the components to make the setting. In addition, to avoid using tools we used handles or fasteners on several screws that are adjusted during changeover.

- Use of graduated scales

  One way of reducing equipment setup time is the use of graduated scales on the different equipment components of the packaging line. Graduated scales are adhesive-backed rules which are installed in those parts of the equipment which undergo changes during a presentation change. The purpose of the scales is to standardize the setting on the equipment, thus avoiding intuition. To achieve standardization the adhesive rules are marked with specific measures of change, based on the presentation. In addition, to make the settings as standard as possible and avoid misreading, a color code was established. In the code all the marks referring to the 50 count are blue and those referring to the 100 count are red. The graduated-scales technique simplifies the settings in the entrance guides of the bundler/wrapper, cartons, in the shippers, entrance guides of the case packer and in the peel plate part setting of the labeler machine.

Operator training design on equipment change

One of the causes of the extensive equipment setup is the fact that it is necessary to wait until the line mechanic finishes making the equipment setup before beginning production. The waiting time should not surprise us because all equipment undergoes changes during changeover. There was no standardized system to make changes in the equipment and it was necessary to wait until the materials for the next lot entered the line before making adjustments on the machine. At this stage the fixtures and the scales have been installed, thus permitting us to make equipment settings without having a sample of the material. With the help of the maintenance team we achieved a recipe-like procedure in which by means of illustrations and references to red or blue marks, step by step descriptions of each machine change were made. Using those procedures the operators can change the unscrambler, capper, labeler, cartoner and bundler/ wrapper without direct intervention of a mechanic. The filler machine has always been set up by the operators, thus leaving the case packer as the only machine that, because of its design, needs to be changed by a mechanic. After these changes, the mechanic's responsibilities are to set up the case packer and to assist and audit the operators in the change of their machine.

Organization and storage of tools

Storage and location of tools are very important to make setup as fast and organized as possible. For this purpose, a cabinet was purchased to store at the packaging lines all tools used during the setup. The cabinet was indispensable to meet GMP and security regulations. The tools were marked and separated in individual cases by equipment, which make easier their identification by the personnel at the moment of the changeover.

The usual way of storing change parts is in cabinets located away from the line (maintenance room). Thus, any eventuality such as lack, or breakage, of any parts would be detected at the moment of change, all of which means delays in setup and final approval of the line. With this in mind we designed a change part cart. A shaded area, the same shape as the part, indicates that the part is in the wrong place. This detection would be done immediately since the cart is kept on the line. Each part is labeled with the corresponding color code (fig. 9).

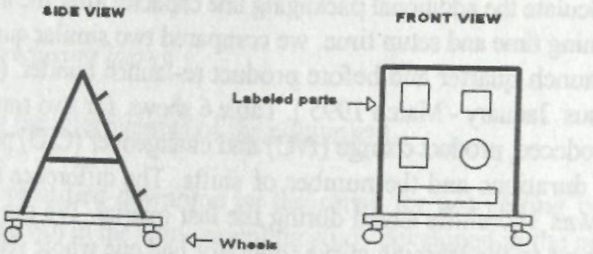

Figure 9. Change part cart

Changeover sheet (near machine)

We used these reference sheets to standardize each equipment setup in such a way that the personnel assigned to it had additional help if needed. This format provides visual representations of change parts in addition to stressing the established color code. A series of basic steps indicates how to make size change on packaging line OTC-1. This format will remain close to the equipment on the line so it will be accessible to any operator on shift.

Actual performance

With the development and implementation of these improvements in both stages, time reductions in the product change and changeover were significant. The simple back to back cleanup (without setup) time was reduced from 3 hours to 1.5 hours. Up to this point, our goals were met and surpassed; afterwards the changeover time was 2.5 hours.

Additional capacity

To calculate the additional packaging line capacity after the improvements in the cleaning time and setup time, we compared two similar quarters: before product launch quarter and before product re-launch quarter. (April - June 1994 versus January - March 1995). Table 6 shows, for two similar quarters, the lots produced, product change (P/C) and changeover (C/O) performed and weeks of durations and the number of shifts. The difference between both quarters was 140 shifts saved during the last quarter. We can attribute this improvement to the learning curve (operator had one whole year running the equipment), the consistency of the equipment setting (a machine speed parameter) and the reduction of the cleaning time and setup procedures.

Table 6. Data for quarters April-June 1994 and January-March 1995

	April - June 1995	January - March 1995
Produced lots	424	420
P/C and C/O	65	64
Weeks	14	12
Shifts	379	239

For example:

For April - June 1994 P/C & C/O - 65 * 8 hr = 520 hr = 65 shifts

For Jan - Mar 1995 P/C & C/O - 64 * 3 hr = 224 hr = 24 shifts

Additional time for production = 41 shifts

Additional units - 3,099,600 jars

@ 75,660 j /shift

Total productive maintenance program

Every company that adopts the TPM approach must accept that the quality and functioning of the equipment must change, the equipment operators must change their way of thinking about the equipment and, as a result, the workplace itself must change dramatically. In general, however, TPM consists of the elimination of the six big losses based on project teams organized by the production, maintenance and department engineer; autonomous maintenance carried out by the production department; planned maintenance carried out by the maintenance department and education to above activities.

Steps for reducing losses

Improving the effectiveness of the equipment

We have identified downtime as the cause for not getting consistent production as shown in the work sampling study developed in the packaging area, specifically in the OTC lines. This study revealed that 65% of the time the machine ceased running. This downtime was distributed as follows: breakdown, 39%; product changes and changeover, 34%; breaks, meetings and training, 18%; and other reasons, 9%. With these numbers we concluded that there are losses in the equipment, and that if we reduce these losses we will increase the production and the effectiveness of the packaging line.

Calculating the effectiveness of the equipment

With the data obtained from the work sampling study and the production logbook, we found that the availability of the equipment is 57%. The performance rate achieved was 92%, which tells us how fast the equipment is running; the quality rate was 99%. The effectiveness of the equipment is the product of these three indicators (OEE= 50.2%).

Because 85% effectiveness is a good index, we can say this equipment shows poor effectiveness. To reach an 85% effectiveness, we need to increase the performance rate to 99%, keep the quality rate at 99% and increase the availability to 87%. It can be observed from these numbers that the availability is the indicator that is holding us under the percentage of the effectiveness that is considered good. Therefore, we must start improving this indicator.

Identifying losses

We used the cartoner machine as an example because the work sampling study revealed that this machine spent more time on hold due to breakdowns. The areas related with the breakdown losses in the cartoner are the leaflet stations, carton dispenser, pockets, plastic chain, timing, change of roll (due to equipment design) and glueing problems. For setup and adjustment we found that the machine had graduated scales to avoid lack of accuracy, but did not have a code per presentation (50 and 100 counts) clear enough to avoid mistakes. Therefore a code of colors was established per presentation. For idling and minor stoppage we identified the sensors, loader jam and the nozzles. The actual speed is 300 jars per minute even though the validation speed is 325 jars per minute. Dirty jars represent the main quality problem.

Reducing losses

To reduce the losses in the cartoner we analyzed the losses individually and trained the personnel in the analysis of the faults and defects that are the result of multiple causes. With the help of the maintenance personnel and the operators a checklist was created to be used at the beginning of the shift. Finally, some procedures to be followed will be suggested when faults, defects or minor stoppages occur.

Breakdowns

Two techniques will be used for the reduction of breakdowns. The first one will be the analysis of the problems found, for which we will use the PM analysis. The other technique is to follow the guides recommended by Shirose using a checklist and training. For optimum conditions in the equipment, the maintenance personnel and the operators in mechanical and technical skills must be continually trained. The training sessions must cover the importance of lubricating the equipment, correct adjustments of the machinery, cleanliness of the equipment, inspection of the equipment, the internal functioning of each machine and their parts, identification of weaknesses in the equipment and setting of the equipment for optimum conditions and specifications. These subjects will improve the skills of the maintenance personnel to assure that they can repair a machine and identify other aspects that need improvement. The maintenance department will have the responsibility of developing appropriate training sessions using their mechanical skills, their experience with the equipment and the specifications of the equipment and share their knowledge with the operators. The training department will provide their knowledge and teaching techniques to develop good training. The purpose of training is to ensure that the operators acquire additional knowledge and get to know better their equipment because eventually each operator will assume more responsibilities with the equipment and should be able to prevent many of the breakdowns, decelerate deterioration and maintain the equipment working and running within its specifications.

A preliminary checklist for the equipment was created to prevent defects, protect the equipment from accelerated deterioration, diminish the possibility of breakdowns and minor stoppages. With these guidelines the operators will be alert to any hazardous situation; thus they will identify any deficiency that could lead to downtime. If any detail that can be corrected is found, the operator will initiate a work order so that the maintenance personnel (or the mechanics) can correct it. Any weakness of the design of the equipment can be included in the work order as well as any suggestion about the material that is being used in the equipment (leaflet, cartons).

If breakdowns occur while the equipment is running the operator will immediately communicate with the maintenance personnel (or mechanic) and he will correct the malfunction. The mechanic should document the malfunction occurrence, how it was corrected, the time spent and any other details that will help to understand what went wrong. The operator will be there as an observer, because it is necessary that he/she understands why the malfunction occurred and how it was corrected.

If the breadown is due to more than one cause, the operator will follow the same procedure and the mechanic will correct the failure and analyze it using the PM analysis (or cause and effect diagram).

Setup and adjustment losses

The setup and adjustment losses were reduced when some SMED techniques were applied. Basically, the cleaning procedure was modified to eliminate some steps and standardize the cleaning process. The equipment was color coded to avoid lack of accuracy in the adjustments when changing from one presentation to another. Finally, the replacement of parts of the suction cup was eliminated.

Idling and minor stoppages

Although idling and minor stoppage losses were diminished with the reduction of the breakdowns, it is important that, if any minor stoppage occurs, the equipment be observed to get enough data to help solve each problem. After getting the data, a mechanic should be called to evaluate the possibility of correcting the stoppage instantly or if it is necessary to analyze these causes. Also, it is important to document each loss that occurs, because it will affect the effectiveness of the equipment. For that reason, it is necessary that each employee understand the importance of documenting each stoppage. If a minor stoppage converts itself into a constant problem or one with multiple causes, the PM analysis can be used to find the roots of the problems.

Reduced speed losses

At this pharmaceutical plant the equipment is processing 300 jars per minute, whereas the line speed of validation is 325 jars per minute. When a malfunction occurs there is a tendency to think that reducing the speed will reduce or eliminate the possibility that the problem recurs. Probably the malfunction will be delayed for some time, but if it is not properly addressed (eliminating the possible causes of the breakdown) it will appear again. This will lead us to think that there are two losses present: a breakdown that occurs because all the possible causes were not eliminated and the other loss for the speed reduction which will increase the cycle time. For this reason it is necessary that, at all times, the speed be the same as the validation unless the quality control department decides otherwise.

Quality defects, rework, startup/yield

Quality defects must be corrected; otherwise, a PM analysis or a cause and effect diagram should be done to identify the root of the problems. The equipment in the packaging lines is not enormously affected by start up/yield and rework losses. However, these losses were reduced by using some SMED techniques.

Team works and meetings

Our teams will consist of:

- One engineer to give technical support. He must be part of the maintenance staff.

- One maintenance technician to identify the technical viability of any issue. He will discuss each of the modifications or repairs made to the equipment so that the operators understand what happened and how the problems were solved. He should also make sure how the repair was done and that the modifications or repairs made are the correct ones.

- Five machine workers to identify the possibility of improvements.

In this stage team meetings should be held weekly. A team will choose a group leader to direct the meeting. The meeting will be a training session to discuss the problems found and the corrective actions.

Autonomous maintenance

First stage

- Initial cleaning
- Elimination of sources of contamination and inaccessible areas
- Cleaning and lubrication standards

Review the first stage

Second stage

- Overall inspection
- Autonomous maintenance standards

Manager's model

To implement the program at the company it was necessary to establish an equipment model. The director, facilitator and engineering team (Packaging technology group) must work as a team to establish an effective model which can provide for the majority of the circumstances that the operators will have to deal with while implementing the program. The model should serve for training purposes and be technically understandable for the operators.

Educational phase

The PM group leaders should receive training on how to generate a CAPD cycle. Everyone involved in the development of the pilot model is responsible for the development of this training: the director, the facilitator and the maintenance and engineering personnel. For the first part of the TPM plan (six big losses reduction) the PM analysis is used. This technique uses a certain form of root cause investigation and thus it differs from the CAPD cycle. Another technique for root cause investigation is the fishbone diagram, which can also be used as a training tool to encourage the analytical knowledge of the operator. The CAPD cycle is used for each criterion that is targeted. It is carried through to completion.

Types of education

Education must be conducted carefully because it will be the first step to stimulate the operators. The facilitator should develop lectures with information supplied by the program director on subjects related to the actual plant breakdown situation. The point is to sell the need for TPM in the plant. In this area the superintendent can help by informing the groups about how much money is being lost due to breakdown problems, among other things. The maintenance department has a very important role in this step. In the work sampling study, certain breakdown causes stood out by way of the Pareto analysis. A few simple ones must be chosen to be used to begin the training that will lead to the freeing of maintenance personnel so that they can attend to the new job requirements that the operators will be generating.

Audit

Stepwise education will be a big help in the implementation of autonomous maintenance. A complete understanding of the audit system will help the operators to understand the goals and accomplishments that are sought in each step. The auditor's group for the OTC line in the packaging department could consist of the facilitator, the director, a member of the packaging technology group and someone from maintenance.

Initial cleaning (Step 1)

Because this company is a pharmaceutical, some of the things developed during implementation are already there but were changed with the TPM approach. After the training, or education, lists should be developed. For each list there is a tag which assigns responsibilities and documents tasks to be executed, completion dates and other pertinent information for the identified area.

Quick response system

To develop a quick response system, the maintenance department should have the goal of answering at least three tags daily. The list of defects could include areas where the cartoner equipment has oil loss, glue, dust or grease accumulation that could be affected by cleanup time reduction. The question list should be used to get the maintenance personnel to answer questions related to equipment function or possible improvement suggestions, which, because of their busy schedule, they would not have time to answer or explain otherwise.

Another list should be made with a view to implementing step 2. It should provide a guide for accelerating the identification of these sources to make it easier to eliminate them. Some of these sources are metal chips, lube oil leakages and broken or hardened hoses. Tasks in which these problems can be found could be cleaning, lubricating, inspecting and other routine operations.

How to proceed

Step 1

During this phase, discussions should be included concerning safety and the pertaining equipment, such as ear plugs, safety shoes, and others. At the same time, it would be wise to discuss and train the personnel on the use and reasons for using the Plexiglas covers and other guards which are part of the equipment.

Step 1 (Audit)

In this step we use audit sheets (questions).

Elimination of source contamination and inaccessible areas (step 2)

During the initial training for the implementation of this step, the maintenance personnel should include lectures designed to introduce the operators to a better understanding of the equipment. Manufacturer specifications, instructions for the orbital small center (OSC; S-4760, S-4761) or the machine technical manuals could be used to detail how the machines work. In the cartoner machine, various items from the checking list can be developed toward the reduction of the six big losses, such as removal of glue from nozzle area, cleaning of oily or greasy areas. Cleaning and lubricating should not exceed 2% of the total hours worked. This time can be used as a starting guide and later be evaluated to either increase it or reduce it if necessary. As a guide to begin with, certain established points in the protocol (06-60-04) which detail the cleaning procedure could be verified.

How to develop (step 2)

After implementation of this step the line experienced a significant reduction in cleanup time. At this point we understood that enough time had elapsed, and that an evaluation had to be made to determine whether cleanup time had to be reduced or increased. To eliminate the need for a file we proposed extracting much more information from ELKE, which can produce reports exactly as we need them, such as schedule, parts, failure time, failure quantities and others.

Activities

Any cartoner machine area which has, or could have, a source of contamination should be analyzed and improved with a system to eliminate or prevent its dispersion. An example of this kind of source of contamination would be a nozzle covered with glue.

Step 2 (Audit)

The audit step is very important because it can heighten interest in the process or wipe out what little interest might be left. Operators should not be overburdened. We need to encourage interest and desire to improve equipment.

The subsequent steps will be conducted as the previous two. This company, being a pharmaceutical facility, already does many of the things that this program recommends, maybe with a different name, but in essence the same. Providing a system that clearly details the specific production functions is an advantage of this program. For a long time it has been known that the same breakdowns were the result of minimum defects and it was questionable whether to wait for a mechanic to adjust a bolt when no great skill is required to do this. The reason for this situation is the belief that "this is not part of my responsibilities and if I do it, what will the mechanic do?" These and many other attitudes should be challenged upon implementation. To achieve an absolute success in the implementation of the program, we need to have a complete interaction between the autonomous maintenance and planned maintenance.

Maintenance in the company

The maintenance staff of the packaging department at our company has three main functions: being in charge of the equipment maintenance, fixing of the equipment every time a breakdown takes place and making major changes in the setup (change over and back to back). Since the operators or the production crew will be freeing the maintenance department of many tasks, the mechanics will have to spend this time looking for maintenance improvements. The autonomous maintenance will allow the maintenance department to analyze their tasks with the purpose of eliminating the possibilities of equipment failures. The checklists developed will be edited by these employees, who will also check the maintenance frequency, lubricant standardization, nuts and bolts, periodical inspection by the operator, and training production personnel in the maintenance techniques. Equipment failures will be pointed out and these employees will be responsible for fixing faults which need technical support.

Quick response system

A system, where the operator and the mechanical technicians work in direct contact would be convenient. On the basis of that, we suggest that the mechanical technicians continue in the area as they usually do and that the company supplies them with a computer loaded with the maintenance software known as ELKE to facilitate information handling, data entry and the information analysis they will do.

Procedure to be followed in case of equipment failure

If the operator can handle it

Every time a piece of equipment stops, the operator must evaluate whether he can fix the fault. If he can, he will fix it and then call the maintenance staff to check for the fault that was fixed. The maintenance staff people will take data such as the symptoms before the failure took place, parts involved, how the failure was fixed and any other information that would help in planning prevention activities. The mechanical technicians verify the conditions that produced the failure in similar equipment to avoid the breakage. Then, the technicians will decide whether editing the computerized program for adding maintenance activities and to locate them in the frequency would be adequate. Otherwise they submit the facts for evaluation to decide whether or not to include them as a standard for autonomous maintenance.

If the operator cannot solve it

If there is a need of a high technical capability to solve the problem, the operator will call the maintenance department. This department will fix the fault and take notes of possible symptoms before the breakdown took place. This department will also verify the conditions that caused the failure in similar equipment to avoid the same failure for the same reason. Then the mechanical technicians will consider whether to edit the computerized system (ELKE) that the company owns for adding the activities. It is important that all steps are developed as soon as the failure occurs. If any abnormality occurs, such as a defective area or any source of contamination appears, the routing established procedure shown in the tag should be followed.

Activities keyed to early discovery of abnormalities

Time-based maintenance

The maintenance department software has the advantage of printing a report when the frequency of the equipment maintenance is overdue. The software is already being used by the maintenance staff. However, they should be trained once again in the data entry of activities and breakdown symptoms. The maintenance staff will have a meeting in which they decide what activities could be added to the maintenance based on the experience and the frequencies in which the same breakdown occurs. The PM analysis could help them in the decision. It is important to eliminate useless inspections. For example, many manufacturers decide to apply a frequency higher than necessary to protect the equipment. We recommend making an analysis to investigate the possibility of modifying those frequencies.

Condition-based maintenance

The equipment needed to apply predictive maintenance is very expensive and high technical skills are required to use the equipment. With this in mind we recommend using time-based maintenance. After the TPM implementation it would be useful to evaluate the possibility of buying the equipment for predictive maintenance and include it as a method of predicting failures. Condition-based maintenance uses two diagnostic methods: simple analysis and precision diagnosis.

Simple analysis includes measurements made with a simple vibration gauge such as a machine checker or shock pulse meter to determine whether any abnormality is present. All simple analysis should be set up so that the factory floor equipment operators are able to handle it.

Precision diagnosis, on the other hand, uses tools such as high precision gauges to find the sources of vibration and to measure and analyze frequencies.

Goals

· To estimate where abnormalities will occur without disassembling the equipment.

· To permit quality checks of the repairs already made to overhauled equipment.

· To permit estimation of repair periods.

· To reduce maintenance costs by eliminating periodic overhauls

Activities to shorten repair time

Replacement of a worn out or broken part in a group of parts already assembled could cause inadequate adjustment between parts, most probably causing excessive vibrations, which in turn could cause a malfunction in the equipment as a whole. Sometimes it is easier to replace a complete set of parts (which could have been affected by a single breakage or worn out part) than to disassemble various parts with the purpose of replacing only one. To keep a fair supply of spare parts in stock, we should check how often these parts are replaced.

Because the software used by the company in the maintenance area is programmed to generate the list of parts that should be bought, the software should be modified to accommodate the maintenance needs. It is recommended that a Pareto analysis be done to identify the parts that most frequently wear out or break. To reduce the time used in changeover and back to back in the complete production line, storage cabinets were designed to keep in stock some spare parts that would be replaced with these changes. In these cabinets we can also include parts more frequently needed and have them handy when needed. It is recommended, if possible, to identify the parts to reduce the possibilities of mistakes to standardize nuts and bolts.

Lubrication management

Just as for nuts and bolts, greases and oils should be standardized to minimize the possibility of lubricating the equipment with a lubricant that does not fulfill the manufacturer's specifications. Another wise practice could be to identify lubricating points with the specific oils and grease types used in order to avoid mistakes or an accelerated wear out of the equipment.

System for collecting and using maintenance - Related information

Even though the company has a program to document corrective actions, breakdowns and, in general, all the necessary information to have a clear idea of the changes and the maintenance performed on the equipment, the mechanics do not use it efficiently. The mechanics document in general terms and they do not include minor repairs. It is necessary to emphasize the importance of documenting, and these responsibilities must be assigned to them.

The implementation part concerning planned maintenance could be implemented simultaneously with autonomous maintenance. This planned maintenance must have effective communication with the autonomous maintenance because one depends on the other to establish effective standards to follow. The concept of "I run it, you fix it" must be avoided; as we mentioned earlier the TPM does not end right here. On the other hand, it is a whole new concept to run businesses concerning the production and maintenance departments.

Preventing dropouts from TPM activities

It is very important to keep the groups highly motivated for the program to be successful. There are warning signs that must be watched that could signal the impending reassignment of group individuals.

Managers must recognize the following dropout:

- Frequency and time spent in meetings are reduced.
- Only certain operators consistently participate in meetings.
- Excessive disparity between action plans and actual performance.
- Operators are concerned with nothing but cleaning.
- Insufficient progress is made with remedies and preparation of standards because of poor technical capability.

Managers must recognize these signs by addressing the following causes to help delinquent PM groups in various ways:

- Not enough time is available to develop the activity because of tight production plans.
- The problem exists in a small group configuration.
- Too much equipment is assigned to a small number of operators.
- The problem is the group leader's leadership and technical potential.
- The problem is related to the operators.
- Because of poor technical capability, the PM group cannot understand how to proceed with improvements and how to prepare standards.

After identifying such problems, managers should take suitable actions as soon as possible, such as restructuring group activities and their scheduling, reducing the amount of equipment allocated, correcting technical weaknesses, and reinforcing assistance from maintenance personnel.